EXHIBIT I

IN THE UNITED STATES DISTRICT COURT

OF THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
BARBARA VIGNOS-WARE Plaintiff, vs. ETHICON, INC., ET AL. Defendant.	Civil Action No. 2:12-cv-00761

--- This is the Deposition of VLADIMIR IAKOVLEV, MD, taken at the Hilton Hotel, 145 Richmond Street West, Toronto, Ontario, on the 4th day of March, 2016.

REPORTED BY: HELEN MARTINEAU

CERTIFIED SHORTHAND REPORTER

Donna Loustaunau)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00666)
)
Patricia Ruiz)
v. Ethicon, Inc., et al.)
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)
Betty Funderburke)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00957)
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Patti Ann Phelps, et al.)
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Dina Sanders Bennett)
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Charlene Logan Taylor)
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Cynthia Nix)
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Barbara Kaiser)
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Carol Jean Dimock)
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Civil Action No. 2:12-cv-00401)
Ana Ruebel)
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Jackie Frye)
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Joan Adams)
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Sharon Boggs, et al.)
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Dina Destefano-Raston, et al.)
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Teresa Georgilakis, et al.)
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Margaret Stubblefield)
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Cindy Smith)
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Maria C. Stone, et al.)
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Diane Kropf, et al.)
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Dee McBrayer, et al.)
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Julie Wroble, et al.)
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Sherry Fox, et al.)
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Joyce Justus)
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Civil Action No. 2:12-cv-00956)
)
Kathleen Wolfe)
v. Ethicon, Inc., et al.)
Civil Action No. 2:12-cv-00337)

A P P E A R A N C E S:
FOR THE PLAINTIFF AND THE WITNESS:
AYLSTOCK, WITKIN, KREIS, OVERHOLTZ, PLLC
DANIEL THORNBURGH, ESQ.
17 East Main Street, Suite 200
Pensacola, Florida 32502
Tel. 850.202.1010
Email: dthornburgh@awkolaw.com

FOR THE DEFENDANT:
THOMAS COMBS & SPANN, PLLC
PHILIP J. COMBS, ESQ.
300 Summer Street, Suite 1380
Charleston, WV 25301
Tel. 304.414.1805
Email: pcombs@tcspllc.com

FOR THE DEFENDANT:
BUTLER SNOW LLP
M. ANDREW SNOWDEN, ESQ.
150 3rd Avenue South, Suite 1600
Nashville, TN 37201
Tel. 615.651.6760
Email: andy.snowden@butlersnow.com

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--- Upon commencing at 5:27 p.m.

(WHEREUPON, the witness was duly affirmed.)

VLADIMIR IAKOVLEV, MD., called as a witness herein, having been first duly affirmed, was examined and testified as follows:

CROSS-EXAMINATION BY MR. COMBS:

Q. Dr. Iakovlev, right before the deposition Mr. Thornburg gave me a flash drive and would that flash drive have your reliance materials for this case?

---EXHIBIT NO. 3: Flash drive containing files reviewed by Dr. Iakovlev in compiling his clinico-pathological report re. Barbara Vignos-Ware.

THE DEPONENT: It would -- it contains medical records I received and reviewed and chain of custody form or forms, depending on if it was one or several specimens.

BY MR. COMBS:

Q. Would the medical records on that flash drive be all the medical records that you

would have reviewed in relation is to Ms. Vignos-Ware's case?

A. That's correct.

Q. And the chain of custody form reflects that you got the sample on November 29, 2015, would all of the work that you've done on this case be between November 29th, 2015 and February 1, 2016, when the report was produced?

A. That's correct.

Q. And there was no synoptic report contained on the flash drive or produced in with the report. Does that indicate that you did not do a synoptic report in this case?

A. Because they were not done for all cases. I just didn't copy them when I had them. So my understanding was since they were not essential for me to form opinions they are part of my records in St. Michael's Hospital. I just did not include any of them on the flash drives.

Q. Did you perform a synoptic report in this case?

A. I don't know. Again, it wasn't essential. It wasn't my goal to complete them. Sometimes I complete them like month after expert

report is served because they're not part of my expert reports and opinions. They're copy of it.
Q. As we sit here today you don't know whether you did a synoptic report in this case, is that correct?
A. That's correct.
Q. I want to ask you about your billing in this case. Would it be a fair statement that you have not kept an itemized bill regarding the work in this case?
A. That's correct.
Q. And is it a fair statement that there is no record of how long you've worked on this case or the specific times or dates that you've worked on this case.
MR. THORNBURGH: Objection.
THE DEPONENT: As with all other specimens I've been doing for two years, this is exactly -- it's impossible sometimes to trace exactly how much time because sometimes I spend ten minutes here, ten minutes there, for one case, for another case. So fragmented.
BY MR. COMBS:
Q. In a prior case you told me that in

your best estimate of the total time that you had spent regarding your report in that case was 15 to 20 hours. Would a similar amount be true in the Vignos-Ware case?
A. Yeah. It will be true for most of the cases. Sometimes it might be less when there's no mesh, specimen is small, records are scant. But most of the reports will fall within 15 to 20 hours.
Q. Is it your best estimate that the amount of time that you worked on the Vignos-Ware report would be 15 to 20 hours?
A. Somewhere in that ballpark.
Q. Dr. Iakovlev, I'm going to hand you what's been marked as an Exhibit 1, which is a copy of your report in this case.
---EXHIBIT NO. 1: Dr. Vladimir Iakovlev's clinico-pathological correlation report re. Barbara Vignos-Ware.
BY MR. COMBS:
Q. And I want to ask you about what your testimony is going to be at the trial of this case regarding the photographs.

A. Yes.
Q. So what is it you're going to tell the jury in this case about the photograph that is at B1a?
A. There is multifilament mesh, in keeping with Gynecare pelvic organ prolapse devices. It's folded, multilayer-ed, it's incorporated by scar tissue in this folded shape and configuration. And there was some parts of fat deeper down. And the top right corner is -- appears to be getting close to erosion site.
Q. And is it true that you received one tissue sample in this case and that would be the one that you received on November 29th, 2015 that was identified as 10-96-104?
A. Yes. I received histological slides of one specimen.
Q. How many slides did you receive?
A. Four.
Q. And how many slides have you created from that specimen.
A. You mean stained further?
Q. Yes, sir
A. Standard is I stained one S100, one

smooth muscle actin. This would be my standard approach.
Q. Now, earlier you said that the tissue that is in B1a is from a prolapse repair device, is that correct?
A. Yes, pelvic organ prolapse.
Q. Do you have any slides that depict the tissue from Ms. Vignos-Ware's TVT? And I've said that incorrectly. Any tissue from Vignos-Ware's TVT-O.
A. So both were excised during the excision of November 24th, 2010. The sampling was done for only part of the specimen. What I saw in the sections was more consistent, as I said, with pelvic organ prolapse mesh, which in this case is Prosima. I cannot rule out completely that there were no pieces of TVT-O in the excision specimen or maybe some pieces within the tissue on the slide, but most of it was in keeping with Prosima device.
Q. Are there any photographs contained in B1a through B13b that you believe are the TVT-O device?
A. No. As I said, I cannot say with certainly that any of the mesh fibers were from

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TVT-O.
Q. Do you plan on testifying at the trial of this case that any of these photographs represent the fiber from TVT-O?
A. No. As I said, I cannot determine to a certainty. I will not testify that.
Q. In B1a you make a reference to the mesh in folded configuration.
A. That's correct.
Q. Can you testify whether that mesh was folded at the time it was implanted?
A. No, I cannot.
Q. What is your basis for your testimony that it is incorporated in a folded configuration in Ms. Vignos-Ware's case?
A. Because it is incorporated in folded configuration.
Q. You will not be able to say when that folding occurred, is that correct?
MR. THORNBURGH: Objection.
THE DEPONENT: Sometime within the timeframe after it was placed in the body and at least a few months before it was excised.

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BY MR. COMBS:
Q. And that could have included at the time of implantation?
A. That's correct.
Q. And would your answer to that question be the same on B1a, B1b and B1-2 for your answer to the folded mesh?
A. Yes. And that answer would be for all of the folded pelvic organ prolapse devices for all these cases.
Q. Dr. Iakovlev, what is it that you plan to tell the jury about the photograph that's B1b?
A. BW1b.
Q. Yes.
A. This is an outline of a most likely configuration of the mesh folds.
Q. Anything else that you plan to tell the jury about that photograph?
A. No. It's just my tracing of the pelvic mesh within the tissue.
Q. And that was going to be my next question. The solid yellow line that is included in that photograph, that would be a line that you

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placed on to this photograph of Ms. Vignos-Ware's mesh using your computer?
A. That's correct. And this would be true for all other images with similar solid yellow line.
Q. What is it you plan to tell the jury about the photograph that is labeled B1-2?
A. This is an enlargement of a previous piece of tissue. It's enlargement of the upper right corner. And this part of the folded mesh you can see is exposed. There is granulation tissue and inflammation on the site of erosion.
Q. Anything else you plan to tell the jury about the photograph that's labeled B1-2?
MR. THORNBURGH: Objection.
THE DEPONENT: No.
BY MR. COMBS:
Q. Dr. Iakovlev, what is it you plan to tell the jury in this case about the photograph that's labeled BW3? Let's go back.
MR. COMBS: Dan, was your objection -- did I say the name of the slide wrong again?
MR. THORNBURGH: No. The objection was to the extent that you're trying to limit him to

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-- I mean -- you don't want a speaking objection, but to the extent that you're trying to say he's only allowed to say what he tells you right now I think may be overrestrictive as he's done a whole report that identifies his opinions. And some of these figures are the same, they're just blown up. And then he gives you a -- with that blown-up figure what is your opinion on that? It's the same opinion to the same slide.
BY MR. COMBS:
Q. What I'm here to do is whatever it is you're going to tell the jury about these photographs I just want to know now.
MR. THORNBURGH: That's not contained within his report?
MR. COMBS: No, that's contained within the report --
MR. THORNBURGH: Well, it's in the report.
BY MR. COMBS:
Q. So, Dr. Iakovlev, let's go to BW3. What is it you're going to tell the jury about that photo?
A. This is the erosion site. With --

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MR. THORNBURGH: Objection.
THE DEPONENT: -- acute inflammation and some -- well, here we can see some bacteria.
BY MR. COMBS:
Q. Anything else?
MR. THORNBURGH: Objection.
THE DEPONENT: That's about it.
BY MR. COMBS:
Q. And I didn't hear. Your voice trailed off.
A. That's about it, but if I'm asked question I can answer more than I just told you because might be able to give a lecture about one picture.
Q. Is there anything else that as we sit here today you plan on telling the jury about BW3?
A. No. My intention for this picture to demonstrate the erosion site with some acute inflammation.
Q. Let me ask you a question about how you identify bacterial colonies on this photograph. Are the arrows that you have pointing to, acute inflammation?

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A. No, they're pointing to the whole area. The whole area is acute inflammation and there are some clusters of small coccoid structures which are in keeping with bacteria.
Q. And what is the diagnostic criteria that you used to determine whether there is a bacterial colony?
A. Just my interpretation.
Q. Are there any stains that you could have used for Ms. Vignos-Ware's samples to determine whether -- the presence of bacterial colony?
A. The stains -- they can stain them in different -- depending on gram positive, gram negative. Again many structures can be staining with these stains. They are not specific for bacteria. They identify the difference between them.
However, just to see them that they are there I just need H&E. You don't need more than that to see them.
Q. Were any cultures taken of the bacterial colonies that you identify on BW3?
A. I don't know.

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Q. Did any physician ever make a diagnosis that Ms. Vignos-Ware suffered from an infection?
A. In the mesh?
Q. Yes, sir.
A. Well, I think we discussed this before. If you have chronic wound it's a given there's infection on there. So if somebody describes chronic wound or erosion that implies infection. If it was worded like this I don't remember because it's so obvious that I wouldn't pay attention or wouldn't include it.
Q. Did any physician ever make a determination that Ms. Vignos-Ware suffered from a bacterial infection at the site of her mesh implant?
A. I don't remember, and I gave you reasons why I was not searching specifically for that information.
Q. Did the treating pathologist from the Cleveland Clinic who inspected this same tissue sample make a diagnosis that Ms. Vignos-Ware suffered from an infection?
MR. THORNBURGH: Objection.

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THE DEPONENT: Let me see what was in there. It says acute and chronic inflammation. That's what we say when we see acute inflammation, implying that there is a bacterial infection.
BY MR. COMBS:
Q. So is it your testimony that if Dr. Chen had diagnosed an infection in Ms. Vignos-Ware's tissue that the way he would have referred to that infection would be by saying acute and chronic inflammation and not using the word "infection"?
A. That's correct. That's what we call. I go for frozen section they give me a sample. And orthopedic surgeon asks -- we don't even talk about infection. Our communication is are there neutrophils or no neutrophils? And everybody understands what it means, neutrophils. Neutrophils means infection. Once they go beyond specific level then that's acute inflammation.
Q. And you would agree with me that Dr. Chen does not use the word "infection" at any point in this pathology report does he?
MR. THORNBURGH: Objection.
THE DEPONENT: Not in this report. Yes,

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you're correct.
BY MR. COMBS:
Q. Dr. Iakovlev, I want to ask you now about BW4.
A. Yes.
Q. What is it that you plan to tell the jury about this picture at trial?
A. This is a difference again, as we saw before there is a difference of density in the scar tissue. Left side is denser. Inside the mesh it's not as dense and you can see these vacuoles of fluid within. It's a common finding. Once you have this multilayering folding of the mesh the fluid bonds is not as easy, it's disrupted so the fluid accumulates there.
Q. And is there any tissue in BW4 that you diagnose as being loose, connective tissue?
A. What do you mean loose connective?
MR. THORNBURGH: Objection.
BY MR. COMBS:
Q. Is there any tissue -- well, you're familiar with the phrase "loose connective tissue"?
MR. THORNBURGH: Objection.

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THE DEPONENT: I don't use that. Loose, connective fibroid connective tissue, dense scar, this can be misinterpreted and -- so if we're talking about normal loose connective tissue, nonscar, nonedematous I don't. What I see here is scar tissue with some fluid in it. So that will be more precise definition.
BY MR. COMBS:
Q. So no tissue in this slide that you would describe as "loose connective tissue"?
MR. THORNBURGH: Objection.
THE DEPONENT: You have to explain what you mean by loose connective tissue because it can mean many things depending on who is using it.
BY MR. COMBS:
Q. So how do you use it?
MR. THORNBURGH: Objection.
THE DEPONENT: In my -- I would use it only for normal, nonscarred, nondamaged, loose connective tissue with some fat tissue which is not as dense.
So if we talk about connective tissue tendons are connective tissue but they are very dense. And then if we go to fat in a way it's

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also connective tissue, but it's mostly fat. And then you go into the areas which are some fibrous tissue but it's not as dense, but it's still normal. However, if we go to scar we can have denser areas and then we can have not as dense or loose, but I wouldn't use that term because essentially it's a different type of tissue. It's not normal. It's a tissue generated as a healing process. And if we use the same term for normal tissue and the tissue which is reactive tissue this would be confusing. That's why I ask you what exactly you mean by that term.
BY MR. COMBS:
Q. Is there any tissue in BW4 that you would identify as fat?
A. As fat? No.
Q. Anything else you plan on telling the jury about BW4?
MR. THORNBURGH: Objection.
THE DEPONENT: No.
BY MR. COMBS:
Q. Let's turn to BW5. What do you plan to tell the jury about BW5 in this case?
A. In this case, in this picture I can

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show the difference between scar tissue and the fat. So the fat would be indicated on there, the right image.
Q. And let me ask you some questions about that. So, for example, on the right, the one that you've identified with the labels, how far is the fat from the mesh in that picture?
MR. THORNBURGH: Objection.
BY MR. COMBS:
Q. So let's go to the upper, right-hand corner where you indicate the word "fat."
A. Oh, you mean this fiber?
Q. Yes.
A. It's very close. It's few --
Q. Approximately how many microns?
A. Few microns, 20 microns. Like a really thin fibrous capsule around that mesh fiber and then it's fat.
Q. What else do you plan on telling the jury about BW5?
A. Well, I can compare that most of the mesh is encased in scar tissue and that's how nonscar tissue looks as fat here, and then I can tell them about scar encapsulation and bridging

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fibrosis and the difference between fat and scar.
Q. In BW5 where is the point where you say that there's bridging fibrosis?
A. I'm saying it now.
Q. No, no, what point of the slide?
A. Oh.
Q. What location on BW5 are you going to point to, to say is bridging fibrosis?
A. This is the cluster of mesh fibers. This is not a cluster. If we go through this pore, the whole pore is filled with scar tissue. So this is the perfect example of bridging fibrosis. And you can see that fat tissue is trying to make its way there but it's not filling it.
Q. And your testimony at this trial will be, just so the record's clear, when you talked about the cluster, one of the clusters is the yellow object at the bottom, and then the other cluster is the group of yellow at the top of the right-hand picture of BW5, is that correct?
A. Yes, and I marked it on exhibit copy.
Q. And it will be your testimony that those two clusters, as you describe them, are not

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separated by fat?
A. Yes, that's my testimony. And this is example where fat is right next to it. But if we go to other images the entire folded structure doesn't have fat. So the entire structure is all one field of bridging fibrosis throughout, solid fibrosis.
Q. Alright. And so just to make sure that the record's clear on BW5, it will be your testimony at trial that fat does not separate the two clusters of mesh, as you've described it?
A. My testimony will be a demonstration of what bridging fibrosis means and what is the difference between scar and fat.
Q. So my question is are the two clusters of mesh separated by fat?
A. Why are you fixated on these two clusters? It's just a demonstration. We can flip two pages and compare. There's no fat anywhere close in this fragment. This was the only portion I could see fat in the deeper parts here.
Q. And Dr. Iakovlev, my question is, yes or no, are the two clusters of mesh in BW5 separated by fat?

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MR. THORNBURGH: Objection.
THE DEPONENT: I don't see it. I mean. It's clearly here. This is an outline, the fibrous tissue, this is an outline of fat. So this is fat and this is bridging fibrosis. So from this point, this fiber to that fiber solid scar. This is bridging fibrosis. This is my testimony.
BY MR. COMBS:
Q. Dr. Iakovlev, anything else you plan on telling the jury in this case about BW5?
A. No.
Q. Let's turn to BW6. What do you plan to telling the jury at this trial about BW6?
A. I will demonstrate for them the reaction and why it is happening and how it is contributing to all of the changes around the mesh.
Q. Is there any tissue in BW6 that you would describe as loose, connective tissue?
A. At the very edges there might be. This would be a transition into normal tissue, as I said, because I would use loose connective tissue more for normal tissue, normal fibrous

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tissue or fiber connective tissue. So at the very edges there would be transitions so this would classify, but the term is sort of loose. I mean, there's no specific terminology when it can be used. I mean, I think we shouldn't fixate on that word. And we should not use it without specific determination of what it means. As long as we all agree what it means then we can use it otherwise it can mean many things.
Q. Dr. Iakovlev, the record is not going to reflect what you're pointing to. I'm going to give you a green highlighter. Can you circle what it is you're referring to?
A. To what?
Q. I asked you if there was loose, connective tissue and you talked about it being -- and were pointing to the upper, right-hand portion of the picture but the record's not going to reflect that.
A. So for loose, connective tissue will we agree that loose, connective tissue is only normal tissue which has not been damaged previously and it's loose just by anatomical location?

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Q. What do you -- here's my question, BW6, is there loose, connective tissue?
MR. THORNBURGH: Objection.
MR. COMBS:
Q. If so --
A. You brought that term. And before I start using it, because I didn't use it in the report, you need to -- we need to agree what it means.
Q. Do you think that there is no loose, connective tissue in BW6?
MR. THORNBURGH: Objection. He's explained why using that term is inaccurate, unless you both agree on the definition of what it means. I don't know how many times you're going to ask him that.
BY MR. COMBS:
Q. That's the question on the table. Is there any loose, connective tissue in BW6. If the answer is no, it's no.
A. Well, I can't answer the question if I don't know what I'm answering. I have to know yes or no -- anyway, I think I've answered the question. We need to have definition and then we

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can use the term.
MR. THORNBURGH: I'm not trying to tell you but maybe if we put an "X" at the location that you guys are talking about and then maybe say how do you define what that "X" is?
BY MR. COMBS:
Q. That's the next question. Dr. Iakovlev, take the green highlighter and circle the area that you're talking about.
A. So these edges, the very edge is the interface with normal tissue where the mesh scar plate ends. So it can end at different type of tissue. From what I see more likely than not it is transitioning into normal, nondense fibrous tissue, nonadipose, nondense fibrous tissue. There might be fat right next to it. It just didn't make it into specimen because it was excised. It's a very thin sort of layer there so I don't know if it's just an edge of the specimen. And to tell you the truth this would be the -- well, not really good picture to ask me that question.
Q. You've drawn a green line on BW6. And over to the left of the green line there are two white spaces. On the top they are white and

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on the bottom yellow. Do those depict mesh?
A. No, this is just a hole. This is edge of specimen.
Q. And I apologize, I'm talking about to the left of the green line.
A. This?
Q. Yes, sir.
A. Yes.
Q. The two things on the top that are in white those are mesh, correct?
A. Yes, this is all mesh.
Q. Here's what I want to know, how many microns is it from the two white pieces of mesh to the green line that you've drawn?
MR. THORNBURGH: Objection.
BY MR. COMBS:
Q. Approximately.
MR. THORNBURGH: Objection.
THE DEPONENT: 150 microns.
BY MR. COMBS:
Q. And just so the record's clear, from the two white pieces of mesh to the green line is approximately 150-microns?
A. That's correct.

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Q. Dr. Iakovlev, is there anything else that you're going to tell the jury about BW6?
MR. THORNBURGH: Objection.
THE DEPONENT: No.
BY MR. COMBS:
Q. Dr. Iakovlev, I'm going to ask you some questions now about the photographs that are labeled BW7, 8, 9 and 10. Are those photographs in which you have identified nerve twigs or branches?
A. Nerve branches, twigs and fibers.
Q. And what is it that you're going to tell the jury about BW7?
A. Same as before and as for other specimens. Demonstrates that the tissue is innervated, it's alive, it can feel pain. By location, the nerves are in abnormal environment in scar tissue within the mesh. Some of them are normal nerves, nothing wrong with them except for location and position.
Q. I'm going to ask you the same question about BW8, 9 and 10.
A. Yeah, the same answer. I don't see specifically distorted nerves, but I don't know

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what's beyond them. I see distorted nerves frequently so there is a probability that somewhere in that specimen there is a distorted nerve. I don't see neuromas but again I cannot rule it out because I see frequently nerves distorted to a degree as traumatic neuromas are -- that's it.

Q. You do not plan at the trial in this case to point to any neuroma that's contained within BW7, 8, 9 or 10 and claim that it is distorted, do you?

A. I just told you. I'm not.

Q. And you do not plan at the trial of this case to point to any nerves that are at BW7, 8, 9 or 10 and claim that there is a traumatic neuroma, do you?

A. I told you I'm not planning.

Q. Dr. Iakovlev, did you consult with a neuropathologist in regard to Ms. Vignos-Ware's case?

MR. THORNBURGH: Objection.

THE DEPONENT: As with case before, I don't think any neuropathologist look at mesh specimen ever. This would be useless to ask them.

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Again, nerves are normal; location is abnormal. And I'm fully qualified to identify nerves in the tissue.

BY MR. COMBS:

Q. Yes or no answer, did you consult with a neuropathologist regarding Ms. Vignos-Ware's samples?

A. There was no need and it wouldn't contribute.

Q. So the answer is no?

A. The answer is no and I'm giving you the reasons why.

Q. For any portion of Ms. Vignos-Ware's sample did you count the nerve density?

MR. THORNBURGH: Objection.

THE DEPONENT: As I said, if I did it would be in my synoptic data notes and there was no need for that to produce the expert report. I don't base my opinion on the density. I don't know. I cannot say either to you yes or no.

BY MR. COMBS:

Q. At the trial of this case you will not be testifying that you calculated the nerve density for any portion of Ms. Vignos-Ware's

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sample?

A. I will not.

Q. You did not stain any portion of Ms. Vignos-Ware's sample with PGP9.5 or neurofilament stain did you?

A. I didn't.

Q. Let's look at BW7. How do you describe that? Is that a -- the nerve that is depicted in that?

A. Smaller nerve branch with some twigs and some fibers in the background.

Q. And do you know what nerve that branch or twigs communicates to?

A. I don't.

Q. Do you know whether those are sensory nerves?

MR. THORNBURGH: Objection.

THE DEPONENT: I think we've been through that today. More likely than not there are sensory nerves -- I mean sensory fibers in there.

BY MR. COMBS:

Q. Can you point to any fiber or branch in that photograph and tell us that it is a

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sensory fiber.

A. Fibers? That would be difficult because fibers are -- they carry one function, sensory or motor. And by staining you cannot differentiate. Again, I'm not differentiating them -- I'm not differentiating them because it's not my purpose to differentiate based on stain, it's by size. Larger the nerve the likelihood that it's mixed is higher.

Q. And because you did not do the PGP9.5 or the neurofilament stain you cannot point to us any receptors in BW7, 8, 9 or 10 can you?

MR. THORNBURGH: Objection. Mischaracterizes.

THE DEPONENT: I wasn't going to. I mean, that was not my purpose.

BY MR. COMBS:

Q. And I just want to make sure that you answered the question. You can't point to any nerve receptors in BW7, 8, 9 or 10 can you?

MR. THORNBURGH: Objection.

THE DEPONENT: I will not be showing nerve receptors to a jury, you're correct.

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BY MR. COMBS:
Q. Thank you. Dr. Iakovlev, is there anything else that you plan on telling the jury about BW7, 8, 9 or 10 that I failed to ask?
MR. THORNBURGH: Objection.
THE DEPONENT: No, not really.
BY MR. COMBS:
Q. Dr. Iakovlev, I want to ask you about the photographs that are labeled BW11a through BW13b.
A. Yes.
Q. Collectively what do those depict, and then I'll ask you about each one.
A. They are following through the steps how to detect degradation of polypropylene.
Q. And in regard to Ms. Vignos-Ware's case what will your testimony be regarding degradation?
A. It's the same story like 30 years ago, polypropylene degrades in the body.
Q. Will it be your testimony at this trial that Ms. Vignos-Ware's mesh degraded?
A. Yes.
Q. And will it be your testimony at

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this trial that you were able to appreciate that degradation through the light microscope?
A. Yes, just give me one second. Yes, my testimony will be that polypropylene of the implanted device degraded while in the body.
Q. And I want to ask you a question about BW11a. You have two arrows that point to what you term the "degradation layer", is that correct? On the right-hand picture?
A. That's correct.
Q. And how thick is that degradation layer in that picture?
A. This one is one of the thinnest. This is the stage where I start detecting it. So this would be around 1 micron, maybe 1.5. From what I understand, now it's been only a number of months between the implantation and explantation. So considering that short period this bark accumulated relatively fast. It's thin but considering that it's been in the body only -- so it's on November 24th and it was implanted in May. So it's really fast it's growing. I mean, if it was a TVT I wouldn't expect it to be visible by that time. Prosima degrades faster.

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Q. Now, you told us earlier that your testimony at the trial in this case will be that the layer of degradation is between 1 and 1.5 microns, is that correct?
A. Approximately.
Q. And you just said that it's your opinion that Prosima degrades faster than TVT, is that correct?
A. We're going into general opinions, but generally thinner fibers of pelvic organ prolapse devices appear to degrade faster. I don't know if it's size or composition of polypropylene. That's just my subjective -- not subjective but my impression at this point. I don't have data, I don't analyze by this time. But generally the lighter weight meshes degrade faster than heavier weight TVT, TVT-O.
Q. Dr. Iakovlev, what is it that you plan to tell the jury about the photograph at BW11a?
A. Same thing. The polypropylene degrades. In this case it's very thin so the contribution to stiffening is not as great, I mean it just began to grow at that time. But the

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release of chemicals which are produced during the degradation is there. I would expect it to be higher at the earlier stages. And that's exactly what was seen in Ethicon-conducted studies, polypropylene degrades. And exactly the same methods, polarized light, blue granules.
Q. What is it you plan on telling the jury about the photograph at BW11b?
A. The way it looks in polarized light -- see because it's so thin I would rather show BW12b where it became separated. So now you can see clearly that there is a layer of altered polypropylene which peeled off.
Q. Okay. Well, let me keep going so that I know. Are you going to say anything about BW11b? And if so what?
A. I probably wouldn't show it.
Q. Okay. Let's go to BW12a then. What is it that you plan to tell the jury about BW12a?
A. This picture is kind of pale. When it's blown up it will be easier to show the degradation layer. Why it's so pale?
Anyway, there was a layer of polypropylene -- of degraded polypropylene peeling

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off and it's more visible in BW12b so I would show it together, two pictures together.
Q. And is there anything else that you plan on telling the jury about BW12a or BW12b?
A. No.
Q. And the layer that you're talking about is, for example, the layer that's between the two arrows on the right-hand picture on both of those?
A. Say it again.
Q. The layer that you're referring to, that's between the two arrows?
A. Yeah, it's more visible, better shown in BW12b.
Q. And is that layer also 1 micron to one and a half microns thick?
A. Yeah, approximately.
Q. Anything else you're going tell the jury about 12a or 12b?
A. No.
Q. What is it you plan on telling the jury about 13a and 13b?
A. This is a blow up. You can see the degradation layer peeled off slightly and there

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are blue granules in it. And the interesting thing is that this degraded layer is low, it doesn't have core any more. So somebody cannot claim that those blue granules came -- are coming into the image not because they are in the degraded layer but because overlapping core. Clearly there is no core. The core floated away.
Q. And I didn't hear what you said. You said the core floated away?
A. Yes.
Q. And how is it that the core floated away?
A. During processing.
Q. Is that during the microtoming of the slide?
A. After that.
Q. So the slide was cut and at what point did the core float away?
A. So when the slide is cut the core doesn't stick well to the glass slide. The only force which is holding it, that central portion of the core, is stickiness to the bark layer because the bark is held by the tissue. And once it starts peeling off, either core or bark layer, it

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starts curling up because it's not sticking to the glass slide so it's folding and curling. And then when the slide is going from solution to solution this core slowly just get detached and float in the fluid of processing fluid, whatever it is, alcohol or xylene. Some of them stay, some of them float away.
Q. And it's your testimony that that's because it's not attached to the tissue as the bark layer is?
A. That's correct. It is attached to the bark layer and the bark layer is rough so it's holding better to the tissue.
Q. Anything else that you plan on telling the jury about BW13a or BW13b?
A. No.
Q. Dr. Iakovlev. You made a statement earlier about release of chemicals during the degradation process, have you made any calculation about the amount of chemicals that you claim were released in Ms. Vignos-Ware's tissue?
A. No.
Q. Dr. Iakovlev, have the samples that you've taken photographs of in 11 through to 13b

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were they ever submitted for analytical chemistry?
MR. THORNBURGH: Objection.
THE DEPONENT: No.
BY MR. COMBS:
Q. Any testing?
MR. THORNBURGH: Objection.
THE DEPONENT: Well, my testing is histology examination so I did my testing. I did not do additional testing.
BY MR. COMBS:
Q. And when you say "histology testing" are you referring to looking at it under the light microscope and the staining process?
A. And using polarizing filters.
Q. Anything else?
A. No.
Q. No other testing?
A. No other testing. Same way as Ethicon scientists did in 1983. They didn't use anything else, just straining, phloxine. They used phloxine and not H&E and polarizing filters.
Q. Dr. Iakovlev, you have not read any of the depositions in this case, have you?
A. That's correct.

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Q. You do not know what Dr. Walters' testimony was on whether the mesh degraded do you?
A. No.
Q. At the trial of this case you will not be testifying that there were any visible particles from the mesh that are in Ms. Vignos-Ware's sample, will you?
MR. THORNBURGH: Objection.
THE DEPONENT: You mean loose in the tissue.
BY MR. COMBS:
Q. Yes, sir?
A. Not visible. I did not see visible particles.
Q. And the -- because there was no analytical testing of this mesh sample there would be no testing of molecular weight or tensile strength, is that correct?
A. That's correct.
Q. Alright. Let's take a break for about five minutes.
--- Break taken at 6:22 p.m.
--- Upon resuming at 6:30 p.m.

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BY MR. COMBS:
Q. Dr. Iakovlev, there was an explant of Ms. Vignos-Ware's TVT mesh on May 20th, 2010. You do not have any sample from that did you?
A. I don't think there was a specimen because there was no pathology report from that specimen.
Q. You did not review any pathology related to that procedure, did you?
A. No.
Q. Do you have any opinion about why Ms. Vignos-Ware suffered an erosion less than two months after the implantation of her TVT-O?
MR. THORNBURGH: Objection.
THE DEPONENT: Because mesh can erode.
BY MR. COMBS:
Q. Do you have any opinion on what caused that erosion?
A. Mesh. The presence of the mesh.
Q. Is that it? That's the opinion?
A. Well, I mean if there's no indication that there's another lesion, like tumor, I mean what else can it be?
Q. Do you think -- is it your opinion

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that when this erosion happened in less than two months post-implant that that's a wound healing issue?
MR. THORNBURGH: Objection.
THE DEPONENT: Actually wound healing -- we're coming back to the same issue. So wound healing -- the first intention healing is within days, three to four days. I mean you have cuts on your skin, does it take two months for you to heal? If it takes two months you have a problem. But normally normal people a skin incision would heal within days, within a week.
BY MR. COMBS:
Q. Do you know whether Ms. Vignos-Ware's surgical incision site ever healed?
MR. THORNBURGH: Objection.
BY MR. COMBS:
Q. Do you know whether it healed during the period from March 26th, 2010, to May 20th, 2010?
A. I don't know. I cannot tell you. But there is no indication that it didn't.
Q. Do you know whether Ms. Vignos-Ware

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suffered a prolapse during the period between March 26th, 2010, and May 20th, 2010?
MR. THORNBURGH: Objection.
THE DEPONENT: I thought that she had prolapse before surgery, cystocele.
BY MR. COMBS:
Q. Let me ask a follow-up question. Do you know whether her prolapse worsened during the period of March 26, 2010, to May 20th, 2010?
MR. THORNBURGH: Objection.
THE DEPONENT: I don't know if it worsened or changed. You're getting, again, beyond my expertise or my role in this case. I'm correlating clinical picture with pathology. And I didn't provide opinions regarding prolapse.
BY MR. COMBS:
Q. As of May 20th, 2010, Ms. Vignos-Ware's prolapse was severe enough that she required a surgical repair, didn't she?
MR. THORNBURGH: Objection.
THE DEPONENT: I'm not sure exactly what you're asking. If it got that bad between that timeframe -- within that timeframe, or just reached that point from any point of time?

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BY MR. COMBS:
Q. Do you know?
A. I don't understand the question. Well, first of all, it's beyond my role in this case as a pathology expert. Second, I didn't look for it, so I wouldn't be able to answer the question.
Q. Anything else?
A. No.
Q. Will you testify at the trial of this case that Ms. Vignos-Ware is at risk from any mesh that remains in her body?
A. Is at risk for what?
Q. Anything. I'm asking if you will testify to that.
A. Well, I mean at risk for specific symptoms? For mesh related complications?
Q. Yes, sir. Will you be testifying at this trial that Ms. Vignos-Ware is at risk from -- for any mesh-related complications as a result of mesh that remains in her body?
A. Yes, she is. The mesh remains in the body so all pathological changes related to the mesh are still going on.

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Q. What mesh remains in her body?
A. So she had excision of a part of TVT in May of 2010. So the exposed part was excised, the lateral part still stayed.
Then in November 2010 more sling was excised, again on accessible parts. Obviously the obturator lateral ends were not excised, so those stay within the body.
The aim during the surgery in terms of Prosima mesh was to excise as much as possible. And there might still be some portions left.
So technically, we are talking about lateral parts of transobturator mesh and some peripheral portions of the Prosima mesh are still remaining in the body.
Q. Will it be your testimony at this trial that some of the Prosima mesh remains in Ms. Vignos-Ware's body?
MR. THORNBURGH: Asked and answered.
THE DEPONENT: More likely than not, there is still some remaining.
BY MR. COMBS:
Q. Have you reviewed Dr. Walters' testimony regarding whether he did or did not

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remove all of the Prosima mesh?
A. I did not read the testimony. And it doesn't really matter what he testified because it's difficult to actually assure completeness of excision. You're cutting through the tissue.
Q. You were not involved in the explantation of Ms. Vignos-Ware's Prosima mesh, were you?
A. No. You make it sound like if I was present it would be possible to determine if everything is removed or not. I don't think anybody will determine if it was not, even n explanting surgeon. You can try, you can aim, but you never are one hundred percent sure.
Q. If Dr. Walters testified that he removed all of the Prosima mesh during the explantation surgery on November 23rd, 2010, do you dispute that?
MR. THORNBURGH: Objection.
THE DEPONENT: I wouldn't dispute his testimony. That's his impression. He is entitled to his opinion and impression. If it truly reflects what is in -- what is happening that's a different question.

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BY MR. COMBS:
Q. You don't know, do you?
A. I don't. I'm just telling you that the way things are, it's impossible to assure 100 percent completeness of excision.
Q. During the November 23rd, 2010, procedure did Dr. Walters perform a uterosacral ligament suspension?
A. Yes, it was done.
Q. And do you know how that is performed? And I'm not asking you for all the details but do you know the basic procedure?
MR. THORNBURGH: Objection.
THE DEPONENT: Basic procedure is that the uterus or vaginal vault is being suspended internally.
BY MR. COMBS:
Q. In your report at page 7 you state that, "The records indicated that Ms. Vignos-Ware reported dyspareunia. Her husband also reported pain on intercourse and feeling exposed mesh." Is that correct?
A. That's correct.
Q. Do you know whether

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Ms. Vignos-Ware's husband reported dyspareunia that was related to the suture repair that was performed on November 23rd, 2010?
MR. THORNBURGH: Objection.
THE DEPONENT: You mean suture repair or uterosacral wall suspension?
BY MR. COMBS:
Q. Yes, sir.
A. That's internal. These would be details more suitable for a urogynecologist to answer. Now, I don't understand exactly the timing of this question. So you're asking if the symptoms persisted after the excision?
Q. I'm asking if Ms. Vignos-Ware's husband reported suffering pain during intercourse as a result of the sutures placed in the uterosacral ligament suspension?
MR. THORNBURGH: Objection.
THE DEPONENT: I don't see that on the excision. So let me see when it says that. So the penile pain is indicated on the visit of October of 2010. Then the mesh is excised. Oh, okay, now I see. And then there is a suture which was -- or what was believed to be suture, could be

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still part of mesh, which scratched her husband again in 2011.
BY MR. COMBS:
Q. And you're referring to the September 12, 2011, entry that you have in your chronology?
A. That's correct. And then Prolene suture was removed.
Q. And have you reviewed Dr. Walters' deposition testimony as to whether the suture that was used in the uterosacral ligament suspension was causing Mr. Vignos-Ware's husband to suffer the dyspareunia?
A. After the mesh removed or before the excision of November of 2010?
Q. After
A. After yes.
Q. Yes.
A. After the excision his impression was that it was suture scratching.
Q. Yeah.
A. Before the excision it was the mesh which was scratching.
Q. And have you -- my question was,

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have you reviewed his testimony?
A. No, I didn't review his testimony.
Q. You do not know what he says about that visit do you?
MR. THORNBURGH: Objection.
THE DEPONENT: No. As I said, I review only clinical records and I summarize. And it clearly states that there was penile pain before mesh excision, which is attributable to mesh. And after that there was a scratching from suture. Suture was removed. And after that I don't see scratching, or didn't see it in the records and it was gone. And no significant dyspareunia was reported in 2013.
BY MR. COMBS:
Q. In your report at page 8 you state, and I'm talking about the first full paragraph. So you talk about, and I'll just read it very quickly:
"Mesh erosion also caused scratching of the penile shaft for Ms. [Vignos] Ware's husband which caused pain and discomfort during intercourse. This symptom has been termed as 'hispareunia'

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in the literature. This phenomenon is unique for mesh surgeries and was described after the introduction of the mesh for transvaginal placement."
Now, do you believe that that statement is correct?
A. Yes, I do. Hispareunia was a term that came into the publications after mesh introduction. The same phenomenon could have been happening with sutures, but the term "hispareunia" I saw it in the literature only after introduction of the mesh.
Q. And in the last sentence of that paragraph you state, "The phenomenon is unique for mesh surgeries." And is that true?
MR. THORNBURGH: Objection.
THE DEPONENT: Scratching penis against the mesh? Yes. Without the mesh you cannot scratch against the mesh.
BY MR. COMBS:
Q. Can you have hispareunia from a suture?
A. You can.
Q. And in fact Ms. Vignos-Ware's

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husband had dyspareunia from a suture didn't he?
MR. THORNBURGH: Objection.
THE DEPONENT: So my statement is that hispareunia term was introduced after the introduction of the meshes, although it could have been recorded, the same symptom, with the sutures and it produces similar symptoms, the terminology came about after the introduction of the mesh.
BY MR. COMBS:
Q. And --
A. The mechanism is similar but the frequency is clearly different. So the frequency went to the level when the term was invented.
Q. And in Ms. Vignos-Ware's case her husband did in fact suffer from what you term hispareunia as a result of the suture placed during the suspension, didn't he?
MR. THORNBURGH: Objection.
THE DEPONENT: Well, see, if we think about hispareunia as a term used for mesh-related complications then we cannot use it against suture-related complications. At the same time, there is no strict definition of what hispareunia is because it's a more descriptive term in the

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literature.
I have not seen a specific description of what exactly it is and how it is defined. Everybody can define it separately. If you ask me about mechanism of penile scratching it would be different. If you can use hispareunia, it really depends on how we define hispareunia. If hispareunia is only scratching related to the mesh then we cannot use it for the suture.
BY MR. COMBS:
Q. Did Ms. Vignos-Ware's husband suffer from pain during sex as a result of the suture that was placed in her vagina during the uterosacral ligament suspension.
MR. THORNBURGH: Objection. Phil, he's answered the question four times now. You want him to answer it a fifth time?
MR. COMBS: Yeah.
MR. THORNBURGH: Last time and then I'm going to instruct him not to answer the same question over again.
THE DEPONENT: He did and we still don't know if it was part of mesh or suture. The surgeon's impression that it was a suture,

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however, we don't know for sure.
BY MR. COMBS:
Q. And do you have any facts at all to base it on the opinion that it might have been mesh? What medical facts do you base that on?
A. Just experience because mesh exposures are recurrent. They just come back and back and back and back.
Q. And you've not reviewed Dr. Walter's testimony on that have you?
A. I don't think anybody with naked eye can, with certainty say that it's a Prolene suture versus the fiber from the mesh, because they're so similar, unless it's a very long stretch, which never is.
Q. And you do not know whether Dr. Walters testified that it was in fact a suture; and that her husband in fact felt a suture; and that he did in fact remove the suture; and that did in fact solve the problem. You don't know that, do you, because you've never read his deposition.
MR. THORNBURGH: Objection. Asked and answered. Phil, that's the fifth time. I said

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one more time. He answered the question. I'm going to instruct him not to answer the question again. You've already asked the same question.
BY MR. COMBS:
Q. You don't know what the deposition testimony was on that point do you?
MR. COMBS: Dan, you can't have it both ways. Your guy can't speculate about stuff, not read the deposition transcript and then come in and speculate about something internal. Can't do it.
MR. THORNBURGH: He's answered the --
MR. COMBS: If you're going to speculate about stuff at trial you don't know anything about, you have to answer the questions about it.
MR. THORNBURGH: Hold on. You've asked the same question six time now, six times. If you want to ask him what his basis is for believing it could be something other than the suture that's fine, that's a little bit of a different question. But you've asked the same question six times. So I've instructed him not to answer.
MR. COMBS: That's because there is no basis.

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MR. THORNBURGH: Why don't you ask him? Why don't you ask him that? Ask him what the basis is.
BY MR. COMBS:
Q. What's the basis, Dr. Iakovlev?
A. Basis for what?
Q. The basis for your opinion that it's possible that it was mesh causing Ms. Vignos-Ware's husband dyspareunia after the mesh had been removed. What's the basis?
A. The basis is that Prolene sutures are very similar to fibers of the mesh. It's the same Prolene and when it's cut really short and tied, it will exactly have the same appearance. It's a blue solid fiber, that's it. I don't think even if you can -- unless there is a very sharp difference in thickness of the fiber -- of the suture, you can determine if it's coming from the mesh or the suture. If the diameter of the fiber is similar, it's impossible. You cannot determine it even under the microscope. This is my opinion. That his impression might be one thing but in fact what is going on in there might be different.
Q. Have you ever treated

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Ms. Vignos-Ware?
A. No.
Q. Have you ever examined Ms. Vignos-Ware?
A. I examined her specimen not her physically.
Q. You were not present when Dr. Walters performed an excision of the suture from Ms. Vignos-Ware in 2011 were you.
A. If I was present?
Q. You weren't present were you?
A. No.
Q. And did you believe you were in a better position to opine on that issue than Dr. Walters?
MR. THORNBURGH: Objection.
THE DEPONENT: What I'm saying that decision if it was a suture or fiber of the mesh at this point is a speculation. Either it's in transcript of a testimony or elsewhere, because they're so similar. I see them all the time. Sometimes the suture is used to remove the mesh. So my opinion as a pathologist who examined both sutures and mesh fibers under microscope is that

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if the suture gets to the thickness of mesh fibers it's impossible to determine. Whatever anyone says, it's impossible -- and this is my opinion as a pathologist who examines these things under a microscope.
BY MR. COMBS:
Q. And so my question is who do you think is in a better position to make that determination, you or the surgeon that actually operated on her?
A. To make determination if it's possible to determine what is suture and what is mesh?
Q. Yes.
A. Me, because I'm examining under the microscope, unless he indicated that it was drastically thicker.
Q. And in regard to the procedure that was performed on September 12th, 2011, you never examined anything from that under the microscope, did you?
A. The removal of the suture?
Q. Yes, sir.
A. No.

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Q. You haven't examined anything from that procedure have you?
A. The only thing I'm saying it's impossible to say one way or another, that's my opinion.
Q. And you're providing that testimony based upon a patient that you never saw regarding a sample that you never examined, aren't you?
MR. THORNBURGH: Objection.
THE DEPONENT: No. I'm providing that opinion based on examination of other sutures and other meshes. That's my basis because I see that under microscope over and over again.
BY MR. COMBS:
Q. This sample you did not examine did you?
MR. THORNBURGH: Objection.
THE DEPONENT: No, but I'm not saying that it wasn't suture. I'm just saying that it could be suture or could be not. And either way since we don't have the specimen we cannot answer the question with certainty now because there is no specimen.

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BY MR. COMBS:
Q. Do you plan on offering any testimony at trial that what Dr. Walters removed from Ms. Vignos-Ware's vagina in September of 2011 do you plan on providing any testimony that that was in fact mesh?
A. No.
Q. Dr. Iakovlev, you have a section in your report that you talk about dyspareunia, it's on page 7 and page 8.
A. Yes.
Q. Have you made any investigation of Ms. Vignos-Ware's medical history to determine whether she had other factors that could contribute to dyspareunia?
A. We're going back in the same loop. I'm not a clinical treating physician. My role here is to correlate what was in the records and what was in the specimen. Clinical investigations led to mesh excisions. I ended up with a specimen and I correlated with clinical records. I don't do clinical differential diagnosis based on the records. You're asking me something I don't do.
Q. Have you been provided Dr. Walters'

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testimony regarding his interpretation of the pathology report that's been marked as Exhibit 2?
---EXHIBIT NO. 2: Pathology report re. Barbara Vignos-Ware.
THE DEPONENT: Well, you know I didn't have any depositions or any testimony.
BY MR. COMBS:
Q. Dr. Iakovlev, I want to ask you a question about a statement at the bottom of page 6 of your report.
A. Yes.
Q. You state, "It is further my opinion that any residual parts of the mesh which were not removed during the excision surgeries continue to pose a risk for mucosal erosion." I want to ask you about the arms of the TVT-O device. You told us earlier that they were not removed, is that correct?
A. That's correct.
Q. Are the arms of the TVT-O device that,were not removed placed in a point where there's,vaginal mucosa?
A. Well, the intent was to remove as much as possible but, again, I don't know how

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close they are. So any residual parts means I don't know. If there are any residual parts they are at risk to be exposed. Could it be parts of TVT-O? Can they migrate to become that close? Could it be parts of Prosima? If there's any mesh any reasonable distance to the mucosa sooner or later, they can become exposed.
Q. Do you have any evidence that the arms of Ms. Vignos-Ware's TVT-O mesh are at her vaginal mucosa?
A. I don't know, that's why I said any residual parts. But I don't know if there are any or not, but if there's anything left and if it's close it can become exposed.
Q. Are you going to offer any testimony at this trial that Ms. Vignos-Ware's mesh did in fact migrate?
A. Parts of the mesh migrated, that's why it became exposed.
Q. Did Ms. Vignos-Ware go to the emergency room approximately ten days after her mesh had been placed?
MR. THORNBURGH: Objection.
THE DEPONENT: Yes, there was

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post-operative bleeding.
BY MR. COMBS:
Q. And do you know what was the cause of that post-operative bleeding?
MR. THORNBURGH: Objection.
THE DEPONENT: It's not clear because the description was that the post-operative incision line healed well. Apparently they did not see mesh exposure at the time. It's a clinical question.
BY MR. COMBS:
Q. You do not know the answer?
A. I don't have an opinion.
Q. You don't have Ms. Vignos-Ware's deposition so you wouldn't know what she says about why she had to go to the emergency room on May 30th, 2010?
MR. THORNBURGH: Objection.
THE DEPONENT: No, I wouldn't.
BY MR. COMBS:
Q. In your report you refer to the mesh being bunched up in the middle and twisted, is that correct?
A. In my report or clinical

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description? I mean in my description or clinical description?
Q. It says it in your description. You say, "Intraoperatively the mesh was exposed in two places. No suture or mesh found in the bladder. Mesh was bunched up in the middle and twisted."
A. I just copied it from the record.
Q. Do you know why the mesh was bunched up in the middle and twisted?
A. Because it can. Because it's defectively designed.
Q. Do you know why Ms. Vignos-Ware's mesh was bunched up?
A. Because it can. Because it's designed the way it allows to do that.
Q. Do you have any information at all regarding Ms. Vignos-Ware's activities within the month following her Prosima?
A. It doesn't matter. If it was a well-designed device it wouldn't bunch up with any activities. Are you implying that the device should limit somebody's activities?
Q. Do you believe that there are no limitations placed on somebody's activities

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following the implantation of a Prosima device?
MR. THORNBURGH: Objection.
THE DEPONENT: Immediately after surgery? There are some protocols.
BY MR. COMBS:
Q. Do you know what those protocols are?
A. No.
MR. THORNBURGH: Objection.
BY MR. COMBS:
Q. You do not know whether Ms. Vignos-Ware's mesh was bunched up during the implantation procedure, do you?
MR. THORNBURGH: Objection.
THE DEPONENT: I don't. Again, it bunched up because it can either during implantation or later on. Since it's designed in a way that it can bunch up, it can bunch up. Let's take about five minutes break.
--- Break taken at 7:04 p.m.
--- Upon resuming at 7:08 p.m.
BY MR. COMBS:
Q. Dr. Iakovlev, I want to make sure I remember to ask you these questions. So in

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relation to Ms. Vignos-Ware's treatment you were not present for any part of any procedure performed on her, were you?
A. That's correct.
Q. You have not spoken to any of her treating physicians, have you?
A. That's correct.
Q. You never saw her mesh in vivo?
A. That's correct.
Q. You played no role in preparing the specimen for pathological review at the Cleveland Clinic?
A. That's correct.
Q. And do you know what the protocols were at the Cleveland Clinic for preparing her specimen for pathology?
A. The appearance of the slides did not indicate that there was any deviation from standard protocols. It was properly processed, properly fixed.
Q. And the tissue would have been dehydrated?
A. It would be fixed, dehydrated, rehydrated, put in xylene and paraffin, covered --

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stained, coverslipped.
Q. And is the fixative that would have been used formalin?
A. Yes.
Q. I wanted to ask you regarding the mechanisms that you had previously testified about that can cause erosion. Would you have an opinion at this trial which specific mechanism caused Ms. Vignos-Ware's erosion?
A. Well, I testify different factors contribute -- playing role within the mechanism. So the specific mechanism is combination of factors. So do you only deal with the factors?
Q. My question is will you be identifying any one of those specific factors and saying, this is what caused her mesh to erode.
A. But that's what I'm saying, there is no one specific factor because the mechanism is so complex, multiple factors are playing role.
Q. Will the factors that you describe to the jury regarding the mechanisms of erosion be the same that you've testified about in prior cases?
A. Yes.

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Q. And will you single out any one of those factors as the cause of Ms. Vignos-Ware's mesh --
A. No, I will not single out one factor. They are all there. They are around the mesh. Mesh is a foreign body, it cannot be remodeled or resorbed.
Q. That's all the questions I have at this point.
--- Break taken at 7:11 p.m.
--- Upon resuming at 7:16 p.m.
DIRECT EXAMINATION BY MR. THORNBURGH:
Q. Doctor, I want to make sure that the record's clear. You had said that regarding the suture do you recall that that was removed from the apex of Mrs. Ware? Well, let me back up a little bit. The suture that was removed was a Prolene suture, or at least identified as a Prolene suture by Dr. Walters, correct?
A. That's correct.
Q. And the Prosima is made out of Prolene?
A. That's correct.
Q. And Mrs. Ware experienced erosions

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from the Prosima in a number of places, including in the apex.
A. That's correct.
Q. Which is where the suture was removed from, that Dr. Walters called a Prolene suture?
A. That's correct.
Q. And is it fair to say that Mrs. Ware was experiencing dyspareunia prior to the uterosacral vaginal wall suspension?
A. That's correct. Dyspareunia and hispareunia.
Q. And that was already occurring before the uterosacral vaginal wall suspension even occurred, right?
A. That's correct.
Q. And do you recall that the reason the uterosacral vaginal wall suspension occurred was as a result of the need to remove some of the Prosima that was eroding through a number of areas, including the apex?
MR. COMBS: Object to form.
THE DEPONENT: That's correct.

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BY MR. THORNBURGH:
Q. Do I understand correctly that the scratching that Mr. Ware was experiencing was at the same location where Mrs. Ware was experiencing dyspareunia and erosions that occurred prior to the uterosacral vaginal wall suspension?
MR. COMBS: Object to form.
THE DEPONENT: Yeah, somewhere in that area.
BY MR. THORNBURGH:
Q. And defense counsel asked you about some bleeding that occurred post-operatively after Mrs. Ware was implanted with the Prosima device. Do you recall that line of questioning?
A. Yes, I do.
Q. I want to show you something. I'm going to mark as Exhibit number 4, which is the explant and implant procedure done on May 25th, 2010, Bates numbered AULTHMBR00111.
---EXHIBIT NO. 4: Surgical documentation report from Aultman Hospital for the explant and implant procedure done on May 25th, 2010, on Barbara Vignos-Ware. Bates labeled

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VIGNOS-WAREB_AULTH_MDR00111.
BY MR. THORNBURGH:
Q. I've got a couple of sections highlighted on Exhibit number 4. First off, what was the preoperative diagnosis that Mrs. Ware received?
A. Dyspareunia post-TVT insertion.
Q. So was it your understanding that she developed dyspareunia after the TVT-O insertion?
A. Yes, that's what it states.
Q. And then if you look at the operative findings and procedures did Dr. -- did the doctor -- the treating physician identify any erosions? An erosion of the TVT-O device?
A. "Repeat pelvic examination reveals that the transvaginal tape sling was exposed on the patient's right and there was minimal exposure on the left."
Q. So there are multiple places of mesh exposure of the TVT-O device?
A. That's correct.
Q. On the left and the right?
A. On the left and on the right.

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Q. And is the -- the TVT-O device is made from Prolene, correct?
A. That's correct.
Q. And the Prosima is also made with Prolene?
A. That's correct.
Q. Just a thinner fiber?
A. Yes.
Q. Slightly thinner?
A. Just over 100 microns.
Q. And will the tissue reaction to the Prolene polypropylene material of the TVT-O device and the Prosima be similar?
A. Yes, they would be similar.
Q. And the erosion of the TVT-O device began more than two months after the implantation of the TVT-O, is that correct?
A. Could you repeat that?
Q. Yeah. The erosion of the TVT-O device occurred more -- approximately two or more months before -- I'm sorry, after the implantation of the TVT-O, correct?
A. Yes.
MR. COMBS: Object to form.

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BY MR. THORNBURGH:
Q. In fact the TVT-O was implanted on March 26th of 2010, right? Approximately?
A. Yes, march 26th and then --
Q. And then the explant of the device was at the same time that the Prosima was implanted, right?
A. Yes.
Q. And that was how long after the implant?
A. Well, two months after the implantation of TVT-O Prosima was implanted.
Q. And then when the Prosima was implanted if you look at Exhibit number 4, Exhibit number 4 indicates that the doctor used -- used the Vicryl sutures to fix the Prosima, does that look -- is that accurate?
A. That's correct, yes.
Q. And I also want to show you on the next page, page -- the second page of Exhibit 4, Bates number ending in 112, do you see where it's highlighted on the second line at the top beginning with, "I then..."?
A. "I then inserted vaginal retention

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device and inflated the balloon with 30mL of air."
Q. So you understand that the Prosima device comes with an inflatable balloon?
A. Yes. To a degree, yes.
Q. And did you understand -- do you have an understanding that rather than using gauze to pack the vagina after the implant that Ethicon represented that this balloon would allow to provide hemostasis of bleeding?
MR. COMBS: Object to form.
THE DEPONENT: Yes. It would also keep the mesh flat.
BY MR. THORNBURGH:
Q. And also to keep the mesh flat. And does this operative report suggest that Dr. Hamilton was attempting to follow the recommendations and training of Ethicon?
A. That's what it appears from the description. And Vicryl is a resorbable suture.
Q. And in your review of Mrs. Ware's medical records, and in your review of the pathology, and your pathological findings, did the balloon that was used in the Prosima keep the mesh

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flat?
MR. COMBS: Object to form.
THE DEPONENT: Well it certainly folded, so if the balloon kept the mesh flat then it folded after the balloon was removed. It certainly wasn't flat when it was removed.
BY MR. THORNBURGH:
Q. And if you look at the operative report, does the operative report indicate in any way, you can take your time to review it, does it indicate in any way that Dr. Hamilton implanted the Prosima all bunched up?
MR. COMBS: Object to form.
THE DEPONENT: See the stitching of the edges indicates that it was secured during the surgery. The way it is described here -- so he inserts Prosima anteriorly and secures it with Vicryl suture, and then tucks the wings into correct anatomical location and then secures them with Vicryl again. So he's stretching it, putting it in a flat configuration. And then closes incision and puts the balloon. So if we analyze all of this more likely than not the bunching up occurred after the Vicryl sutures were resorbed,

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which takes several weeks.
BY MR. THORNBURGH:
Q. So does your review of the operative report indicate to you that the mesh was put in in a matter that should have kept it flat but that at some point after the Vicryl sutures absorbed the mesh began to ball up and bunch?
A. Yes, that's correct. I mean this is the explanation to reasonable degree of medical certainty basing on all these facts, that it was stretched, it was secured and the balloon was placed. So the only way it could became loose again and gather together is that the sutures were not holding it any more, and Vicryl is a resorbable suture.
Q. And does your review of the operative report and your review of the pathology slides indicate to you that at some point after the balloon was used to -- as part of the Prosima device that the mesh became bunched up?
A. After the balloon was removed and after the Vicryl sutures resorbed.
Q. And is it your understanding that Mrs. Ware had a number of mesh erosions?

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A. Yes.
Q. Those erosions began in the TVT device, is that your understanding?
A. That's correct. It started with TVT with first device, and then second device is inserted and then second device became exposed.
Q. So her tissue responded the same way to the TVT-O device as it did to the Prosima device, is that fair?
A. Yes, both devices became exposed.
Q. And does Mrs. Ware still have the obturator -- still have mesh at least in her obturator?
A. Yeah, at least in both obturator spaces. Yes.
Q. And does that put her at risk of suffering future harm as a result of the tissue response that she has already experienced with both the TVT-O device and the Prosima device?
A. Yes. Mesh is there, all the pathological changes, the scarring, the nerve involvement is there, and especially in the obturator space where the nerves are more abundant and they are larger in there.

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Q. And your review of the pathology material, did that correlate with your review of the medical records which showed that the mesh was bunching?
A. Sorry?
Q. Yeah. Your review of the pathology, and we don't need to look at it again, but you had identified some microphotographs that demonstrated folding of the mesh?
A. Yes.
Q. Did that correlate with your review of the medical records where bunching of the mesh was identified?
A. Oh perfectly. That was exactly what was described in the intraoperative report. That's what I saw in microscopy.
Q. Is that also evidence of migration?
A. Yes, actually it is. It was flat, secured and sometime after Vicryl sutures resorbed, it all bunched up. So large portions of the device migrated through the tissue to form these complex folds.
Q. Did your pathological analysis correlate with mesh contraction?

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A. Yes. So what I saw, I saw scarring. And we know that scar contracts. And all these layers became compacted during scar contraction.
Q. Can scar contraction cause the mesh to bunch?
A. Yes, it can. It will exacerbate the migration. So migration forms these folds, scar contraction exacerbates it further.
Q. And we won't look at all your microphotographs again, but did your microphotographs, in fact every one of them using H&E staining, demonstrate dense scarring in and between the pores?
A. That's correct.
Q. And did your microphotographs demonstrate bridging fibrosis?
A. That's correct.
Q. Do all of your microphotographs using H&E staining demonstrate encapsulation of the mesh in scar plating?
A. That's correct.
Q. Do those findings correlate with migration?
A. Yes.

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Q. Do those findings correlate with contraction?
A. Yes.
Q. Do those findings correlate with erosion?
A. Yes.
Q. Do those findings correlate with pain?
A. Yes.
Q. Do those findings correlate with dyspareunia?
A. Yes.
Q. Does riding a motorcycle or a bike cause scarring?
A. No.
Q. Does riding a motorcycle or bike cause contraction?
A. No. Scar contraction, no.
Q. Does riding a motorcycle or bike cause bridging fibrosis?
A. No.
Q. Does riding a motorcycle or bike cause erosion?
A. No.

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Q. Does riding a --
A. Unless you have accident and fall and something --
Q. Does riding a motorcycle or bike cause bridging fibrosis?
A. No.
Q. Scar plating?
A. No. And it does not cause nerve ingrowth for sure.
Q. No further questions.
FURTHER CROSS-EXAMINATION BY MR. COMBS:
Q. Dr. Iakovlev, does Ms. Vignos-Ware suffer any pain currently?
MR. THORNBURGH: Objection.
THE DEPONENT: I don't know. The records stop sometime in 2013.
BY MR. COMBS:
Q. And in 2013, the finding that you recorded in your report was no significant dyspareunia at the time, wasn't it?
A. That's correct.
Q. And you do not have any information that Ms. Vignos-Ware suffered pain any time between 2013 and the present, do you?

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MR. THORNBURGH: Objection.
THE DEPONENT: No, it wasn't my purpose.
BY MR. COMBS:
Q. And have you been provided with a copy of Dr. Rosenzweig's IME in this case?
A. IME?
Q. Yes, sir.
A. What is IME?
Q. His independent medical examination.
A. You mean expert report or something?
Q. Yes, sir.
A. No. I don't have any expert reports. I don't have any depositions. All what I have you have on flash drive.
Q. Now, when Mr. Thornburgh was asking you questions, was it your testimony that the Prosima mesh caused Ms. Vignos-Ware's prolapse?
A. No.
Q. Alright.
A. I never said that.
Q. In fact she had prolapse prior to any implantation of the mesh, didn't she?
MR. THORNBURGH: Objection.
THE DEPONENT: Well, the mesh was placed

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to treat the prolapse.
BY MR. COMBS:
Q. Exactly.
A. Yes.
Q. You testified that Ms. Vignos-Ware's dyspareunia was at the same location in 2010 and 2011 didn't you?
MR. THORNBURGH: Objection. Mischaracterizes.
THE DEPONENT: Not sure. I mean dyspareunia or exposure of the mesh?
BY MR. COMBS:
Q. Dyspareunia.
A. I did not testify where exactly dyspareunia was. You can feel it in entire pelvis. When it hurts one point it can radiate.
Q. So you didn't testify in response to Mr. Thornburgh's questioning that her dyspareunia was at the apex of her vagina?
A. I thought we were talking about exposure site.
Q. And so if you testified that her dyspareunia was at the apex of her vagina would that be a mistake?

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A. No. If it's exposed there, there will be feeling of dyspareunia there, but we were focusing on exposure.
Q. Where was Ms. Vignos-Ware's dyspareunia in 2010?
MR. THORNBURGH: And just so the record is clear, so you understand, I think he was answering questions about the hispareunia and location of the mesh exposure --
MR. COMBS: Perhaps I misheard him but I don't think I did.
MR. THORNBURGH: -- and the suture area.
THE DEPONENT: So now I'm all mixed up. Erosion, hispareunia, dyspareunia. So which time? What month of 2010?
BY MR. COMBS:
Q. Are you going to have any testimony at the trial of this case as to the location of Ms. Vignos-Ware's dyspareunia at any time?
MR. THORNBURGH: Objection.
THE DEPONENT: Specific point?
BY MR. COMBS:
Q. Yes, sir.
A. No. Dyspareunia is described in the

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clinical records. If there is any further definition there -- again, it's not my job to do the clinical part.
MR. THORNBURGH: You have one minute left on your rebuttal time, just so you know.
MR. COMBS: No, I don't. I don't have one minute left on my rebuttal time. You can't take time questioning him and say that's my time.
MR. THORNBURGH: You used up all your time.
MR. COMBS: I didn't use up all my time, Dan, that's just not true.
MR. THORNBURGH: You used a lot of it.
MR. COMBS: I didn't use up my time.
MR. THORNBURGH: You get three hours.
MR. COMBS: That's just not true. First of all we haven't been here for three hours. And it's not three hours it's two hours.
MR. THORNBURGH: That's what I meant to say. Are you going to go for much longer?
MR. COMBS: No, I'm not going to go for much longer but it's an untrue statement that I have only one minute. Let's go off the record.
--- Off the record at 7:42 p.m.

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--- Back on the record at 7:43 p.m.
BY MR. COMBS:
Q. Dr. Iakovlev, are you going to testify in this trial regarding the location of Ms. Vignos-Ware's dyspareunia at any time?
MR. THORNBURGH: Asked and answered.
MR. COMBS: Asked but interrupted.
BY MR. COMBS:
Q. Are you going to testify about that at this trial?
A. The location was in the vagina. So dyspareunia is felt in the vagina and pelvis.
Q. Are you going to do anything more specific than that at this trial?
A. No.
Q. Now, is it your testimony that the --
A. Dyspareunia or hispareunia?
Q. Let's start with dyspareunia?
A. Dyspareunia, yes. Vaginal and pelvic.
Q. So are you going to give any testimony, any more specific than that, that it was in the vagina or pelvis?

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A. No.
Q. Now let's talk about the hispareunia. Where was the hispareunia that Ms. Vignos-Ware's husband felt in 2010?
A. Hispareunia where the exposed part is.
Q. And was there an exposure of the TVT-O mesh?
A. There was exposure of TVT-O.
Q. Was there an exposure of the Prosima mesh?
A. There was exposure of Prosima mesh.
Q. Where was the hispareunia?
A. Can anyone tell when it scratches --
Q. That's my question. You're the one that's testifying and offering an opinion about it.
A. I am not offering an opinion. I just copied what is -- we're mixing what is my opinion and what is in the record. The record says "penile scratching", "penile pain". That's not my opinion.
Q. And are you going to offer any testimony at the trial of this case where the

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location of the mesh was that was causing that penile scratching in 2010?
A. I will not offer specific location because I didn't examine the patient, didn't take a history. It's clinical part. What I can say about hispareunia and dyspareunia is what is in the records.
Q. Now, the location of the TVT-O and the Prosima are different aren't they?
A. Yes.
Q. And the location of the TVT-O and uterosacral vaginal vault suspension are different aren't they?
A. To a degree. There would be overlap with --
Q. You believe there is overlap between the placement of the TVT-O and the uterosacral vaginal vault suspension?
MR. THORNBURGH: Objection.
THE DEPONENT: I'm talking about Prosima and uterosacral suspension.
BY MR. COMBS:
Q. That wasn't my question. Maybe I asked the wrong question. My question is, do you

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believe there's any overlap between the placement of the TVT-O and uterosacral vaginal vault suspension?
A. No, they're quite far from each other.
Q. Now, are you going to offer any testimony at the trial of this case that Ms. Vignos-Ware's Prosima was properly placed?
A. Well, we just read the record. I don't see any indication that it wasn't properly placed and it's quite -- it's not my opinion. I can read again what was there. It was stretched. It was put flat and sutures were secured on the edges and then there was a balloon placed.
Q. Are you a urogynecologist?
A. No, I'm not.
Q. Do you have any urogynecological training?
A. No.
Q. Are you going to offer testimony at the trial of this case that the placement was proper?
A. No, but I can see that the edges were secured.

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Q. Now, in response to Mr. Thornburgh's questions, you testified that Vicryl sutures are absorbable, is that correct?
A. That's correct.
Q. And you said that they absorb within several weeks, is that correct?
A. That's correct.
Q. What do you think the time period is for Vicryl absorption?
A. It's variable between the patients.
Q. How long do you think it is?
A. I said weeks.
Q. How many weeks.
A. The answer was weeks. If I say "weeks" it means weeks, if I say "three weeks" it will be three weeks, but I didn't say three weeks.
Q. How many weeks?
A. I'm getting really tired. It's been a very long day and we are running in circles now. Weeks, I don't know how many. It's variable between patients. You cannot narrow the number. If you're trying to pull the number out of me I cannot give you a number.
Q. You don't know do you?

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A. No, I know weeks. This is how we say. Hours, weeks, years. This is common to use in pathology, in medicine, to use this term describing timeframe. Days, weeks, month. This is regular standard way of expressing the time.
Q. Let me ask it this way. Is it more or less than a month?
A. Weeks can be less than a month, can be more than that month.
Q. Here's my question, is the absorption of Vicryl sutures does that occur in more or less than a month?
MR. THORNBURGH: Objection.
THE DEPONENT: It's variable. I said weeks. My answer it weeks.
BY MR. COMBS:
Q. Do you know whether it occurs in more or less than a month?
MR. THORNBURGH: Objection. Asked and answered. He said variable. Depends on the patient. He said a number of different things and he answered your questions.
BY MR. COMBS:
Q. I know he said a lot of different

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things.
A. Sorry, if you're going to at the end of the day repeat the question until I give you just a number, just stop this; that's not fair.
Q. That's not actually what I'm trying to do, Dr. Iakovlev. What I'm trying to do is figure out -- you testified that it took place in a matter of weeks. I just want to know if you know what the absorption period is for Vicryl sutures?
A. I said weeks, that's my answer.
Q. Is the obturator space inside the vagina?
A. No.
Q. Is there any place in your report that you make reference to scar contraction?
A. Yes, and you know that it is there.
Q. Where? You know your report better than I do. Maybe you do.
A. Here we go. Page 7, third paragraph, third line from the top:
"...physiologically scar tissue undergoes contraction. In cases of implanted meshes the scar tissue within

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and around the mesh contracts together with the embedded within mesh device. This leads to tightening in cases of both slings and POP meshes, and further wrinkling/gathering of the POP mesh devices."
Q. Dr. Iakovlev, you talk -- Mr. Thornburgh asked you a number of questions whether motorcycle riding could cause, for example, bridging fibrosis, et cetera. Now here's my question, can physical activities of a patient cause a mesh to be displaced?
MR. THORNBURGH: Objection.
THE DEPONENT: Now we're talking what's the mechanism of mesh displacement and migration. Can physical activities contribute to that process? Possible. But I think the main question is, if it can. So if physical activities contribute to mesh displacement, then the mesh design would limit physical activities.
BY MR. COMBS:
Q. Are you going to offer any opinion at the trial of this case as to whether physical activities of a patient can or cannot cause mesh

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to become displaced from its implantations.
A. I didn't bring it up. I'm not going to talk about physical activities.
Q. Okay. No more questions from me.
--- Whereupon the examination was completed at 7:52 p.m.

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REPORTER'S CERTIFICATE

I, HELEN MARTINEAU, CSR, Certified Shorthand Reporter, certify;
That the foregoing proceedings were taken before me at the time and place therein set forth at which time the witness was put under oath by me;
That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;
That the foregoing is a true and accurate transcript of my shorthand notes so taken.

_____
PER: HELEN MARTINEAU
CERTIFIED SHORTHAND REPORTER.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

VLADIMIR IAKOVLEV, MD DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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